



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re application of: Mooney, et al.

Group Art Unit: 3763

Application No.: 09/329,002

Examiner: LoAn H. Thanh

Filing Date: June 8, 1999

For: MULTIPLE LUMEN ACCESS DEVICE

Commissioner for Patents
Washington, D.C. 20231

PETITION UNDER 37 CFR §1.182 TO RESET DATE OF AN OFFICE ACTION

Dear Sir:

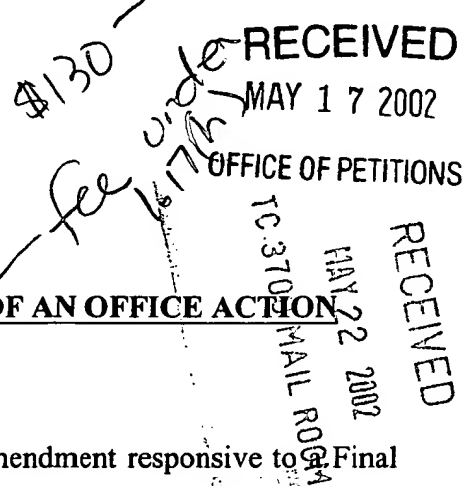
This petition is being submitted concurrently with an Amendment responsive to Office Action dated November 30, 2001. Applicants petition the Office to reset the date of said Office Action to the March 15, 2002, for the reason described below.

This Petition is submitted under Rule 182 because there is no specific regulation in 37 CFR pertaining to this situation. There are provisions in the MPEP directed to similar situations, but Applicants believe this instance warrants separate consideration, as will be explained below.

Attached is the original Office Action and envelope that were received on March 15, 2002 by the law department of a Baxter International branch in Irvine, California. Please see the attached email explaining the circumstances surrounding the receipt of the Office Action, from Diane Branham of Baxter Healthcare Corp. to Lena Vinitskaya of Edwards Lifesciences, the assignee of the present invention. Guy Cumberbatch, the undersigned, spoke with Ms. Branham after receiving and inspecting the Office Action on March 21, 2002, and Ms. Branham indicated that all of papers including the envelope were received in a plastic bag because of their deteriorating condition. It appears that the papers have been passed through an irradiating machine because they are extremely brittle. This is consistent with the increased security surrounding mail service in the Washington D.C. area.

More importantly, please note the post mark on the envelope which appears to indicate that it was sent in a month beginning with the letter "M" in the year 2002. Because of the date of receipt, Applicants believe that the letter was sent in March of 2002.

Based on experience, mail from the Patent Office takes approximately one week to arrive



in California. Therefore, Applicants believe that the letter including the Office Action in question was sent in March of 2002. It was clearly not sent in 2001. If it was sent in March, then more than three months were lost between the *prima facie* date of mailing as printed on the Office Action, and the apparent date of mailing based on the evidence. This is greater even than
5 the shortened statutory period for reply. Accordingly, because this time for response has been lost through no fault of the Applicants, the Office Action date should be reset to the date of receipt, March 15, 2002.

Edwards Lifesciences was previously a part of Baxter Healthcare, but was spun off in April of 2000. The two offices in Irvine are about a half-mile apart, and still maintain some ties,
10 such as inter-office mail. When the present application was filed, it was in the name of Baxter International. Unfortunately, the company recipient for this application was never changed from a Baxter International, although the named recipient and street address remains correct. However, this minor confusion did not have anything to do with the letter being postmarked in March of 2002, or being received on March 15, 2002.

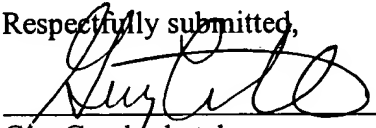
15 MPEP §710.06 speaks to situations when the reply period is restarted, and addresses situations when Office Actions are received late or postmarked later than the mailing date, both of which happened here. In these cases, the MPEP imposes a two-week reply date for petitions seeking to reset dates. Except for that reply time window, the facts above warrant resetting the date. The MPEP speaks to situations where the Office Action was received late but within the
20 statutory period for response. Here, the Office Action was not mailed until after the statutory period for reply was passed. Applicants received the Office Action fully 3½ months after its official date of mailing.

Applicants Petition the Office to restart the Office Action date despite the policy of the MPEP because of the unjust situation that would result. The undersigned contacted the
25 Examiner on March 21, 2002 and explained the situation. The Examiner did not know how to handle the situation and did not indicate that there was such a short period for reply with a petition. Indeed, in 11 years of practice the undersigned has never encountered such a short period for reply to anything in the Office. Both the Examiner and the undersigned presumed that

the Petition, which in this case only affects the extension fee charged, would be filed with the substantive response as a request for a refund of the extension fee paid at the time. Refund requests must be submitted within two *years* of the date of paying the fee, and the undersigned had planned to submit such a request along with payment of the extension fee calculated from November 30, 2001. Unfortunately, the two week reply period in the MPEP was not discovered until it was too late. However, in this situation, Applicants believe that the Office should not follow such a rigid time schedule. The MPEP does not carry the force of law, and in some instances such as here should be used only to guide a just decision.

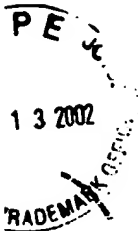
MPEP §710.06 reminds that there is no statutory requirement that a shortened statutory period as here be reset due to delay in the mail or in the Office. Nevertheless, the MPEP provides for a date reset but presumes that the delay is still within the statutory period. When as here the statutory period has passed, Applicants petition for relief from an unduly strict requirement. Whether submitted within two weeks or within two months as now, there is no advantage gained because the reset date would remain March 15, 2002. Further, this application does not gain the benefit of the new term extension laws and the term remains 20 years from the earliest priority date. The delay in the mails is simply lost. The only issue is whether the Office chooses to apply a time period for reply that is unique in the experience of the undersigned. Granted, the undersigned failed to discover in time that there was a relevant MPEP section, but as mentioned above the Examiner was contacted for guidance and none was provided.

Respectfully submitted,


Guy Cumberbatch
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c/o Edwards Lifesciences LLC
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I hereby certify that the above-identified document is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Commissioner of Patents, Washington D.C. on April 30, 2002.

Signed: 



Diane M Branham
03/15/02 08:34 AM

To: lena_vinitskaya@edwards.com, claudia_previde@edwards.com
cc:
Subject: office action

we received in our PO box today and office action for one of your cases dated November 30, 2001. I am not going to try and fax it because it came in a partially shredded envelope and is in pretty bad shape. I was at the USPTO last month and their mailroom explained that a lot of the older mail had gone through irradiation at the post office and that even in the USPTO files a lot of it was in bad shape. I am assuming the reason this is so late is that it was caught up somewhere.

I don't know if your assistants are doing status checks or if they are still being docketed, but if so perhaps you have already gotten a copy of this from the USPTO. If not it's already almost 4 months old. Will send it in intercompany mail today but it will be Monday before you get it as we have only one pickup over here per day in late afternoon.

Diane Branham
Baxter Healthcare Corporation
Patent Administrator/Irvine
949-250-6839

Confidentiality Warning: This e-mail contains information intended only for the use of the individual or entity named above. If the reader of this e-mail is not the intended recipient or the employee or agent responsible for delivering it to the intended recipient, any dissemination, publication or copying of this e-mail is strictly prohibited. If you have received this e-mail in error, please immediately notify us by return e-mail and call (949) 250-6839. Thank you.



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A

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/329,002 | 06/08/1999 | CHARLES R. MOONEY | ECC-5062CIP2 | 7619 |

7590 11/30/2001

LENA I VINITSKAYA
BAXTER HEALTHCARE CORPORATION
P O BOX 15210
IRVINE, CA 926235210

EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 11/30/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED
LAW DEPT.

MAR 18 2002

EDWARDS
LIFESCIENCES

| |
|-------------|
| RECEIVED |
| MAR 15 2002 |
| By _____ |

DOCKET NO.: 5062CIP2
2 MONTH DATE: 1-30-2002
DDD/FINAL: 5-30-2002
Response to Final



COPY OF PAPERS
ORIGINALLY FILED

Application No.

09/329,002

Applicant(s)

MOONEY ET AL.

Examiner

LoAn H Thanh

Art Unit

3763

Office Action Summary

The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 20-24, 26-37, 60-70 and 75-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 20-24, 26-37, 60-70 and 75-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 27 August 2001 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a), (b), or (c).

a) ☐ All b) ☒ Some c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant has not argued which claim is generic and thus, the Examiner is maintaining there are no generic claims.

The requirement is still deemed proper and is therefore made FINAL.

An action on the merits now follows.

Response to Amendment

The drawing objection has been withdrawn in view of the proposed drawing filed 8/27/01. The drawing proposal has been approved.

The rejection under 35 USC § 112, 1st and 2nd paragraph has been withdrawn in view of the amendment filed 8/27/01.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

~~A person shall be entitled to a patent unless~~

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 17, 21-24, 26-29, 30-33, 37, 60-67, 69-70, 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant (U.S. Patent No. 5,472,418).

Palestrant discloses an outer tube (46) See figs. 1-3, 4-9, 10-12. Palestrant specifically fig. 12 shows 2 auxiliary lumen and device lumen. The medical device being the guidewire (50). The flexible wall being 32 and 38. See col. 10.

4. Claim 1-3, 17-18, 20-24, 26,28-30, 37,60, 62, 75-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Young (U.S. Patent No. 5,451,206).

See figs. 1-3, 5-6, 7, 8, 12-16. Young discloses in fig. 8 the lumens ending at different location between the proximal and distal end of the outer tube. See fig. 3, 15, col. 14. Young teaches different materials with different durometers depending on what is required of the strength of the lumens.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 8-10, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palestrant (U.S. Patent No. 5,472,418) in view of Nishijima et al. (U.S. Patent No. 5,092,846)

Palestrant teaches all the limitations of the claims except for the specifics of the device lumen valve. Nishijima et al. teaches a valve device in the analogous art of medical introducers. Nishijima et al. teaches a multi component valve insert as shown in figs. 4-5. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the teaching of Palestrant with the valve insert teaching of Nishijima et al. in order to provide any leakage of fluids from the body which would endanger the patient.

Response to Arguments

Applicant's arguments filed 8/27/01 have been fully considered but they are not persuasive. With respect to the discussion of Palestrant, the Examiner is taking the position that the intended use or functional language in the claims of a device imposes no limitation to the claim in the absence of distinguishing features. It has been held that the recitation that an element is "adapted to" or "is capable" of performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Further, applicant's amended language is interpreted as functional. The claims are being interpreted broadly and considers Palestrant to still read on the claims. AT a particular point along its length, the tube of Palestrant has a cross sectional area which remains substantially unchanged. There is no change without any force applied within or external to the tube.

If there was a device which is inserted then depending on the size of it, it may or may not cause a change in the cross section of the outer tube. Applicant appears to be arguing more broadly than claimed since there is no instrument that has been positively claimed to provide this force. Further, although Palestrant's outer tube is a collapsible Applicant is directed at figs. 3A and 11 and 12. If the tube of Palestrant was completely collapsible then the auxiliary would be closed completely along its length. That however is not the case. Collapsible and flattened does not entirely translate to being closed or

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to the extreme of the situation since it would not be functional to insert if that were the case. It still is capable of meeting the structural limitations depending on the force that is applied whether it is an instrument or fluid which is causing the force. Further a cross-section is taking at one point in time and not as a something is moving to cause it to change. If any force is exerted to the exterior of applicant's invention, it would be collapsible.

~~As to the discussion of Young, "flexible" is a relative term. Although Young~~ discloses that it reduces the likelihood of deflection it does not teach complete reduction. Applicant appears to be arguing the intended use of the device and not the structural limitations which is given patentable weight to an apparatus claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37

CFR 1.136(a)

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on 5:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ~~Angela Sykes~~ can be reached on ~~703-308-5181~~. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

LoAn H Thanh
Examiner
Art Unit 3763

LT

November 16, 2001

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

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CERTIFICATE OF MAILING

I hereby certify that the above-identified document is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on _____

By: _____
Christine Koken

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